U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

William Rowe
GRAS Associates, LLC
11810 Grand Park Avenue, Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001277

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) is granting the request on behalf of ReviveBio, Co. (ReviveBio) that we cease our evaluation of GRN 001277. We received this request on December 26, 2025. We received ReviveBio's notice on May 6, 2025 and filed it on August 13, 2025.

The subject of the notice is autoclaved *Parabacteroides goldsteinii* "RV-01" (autoclaved *P. goldsteinii* "RV-01") for use as an ingredient in sports and "energy" drinks, ready-to-eat cereals (low sugar), yogurt, fermented milk products, ice cream, cereal bars, nutrition bars, nut spreads, and candy containing chocolate at a level up to 1×10^{10} total fluorescent units/serving (excluding use in infant formula and products under the jurisdiction of the United States Department of Agriculture). The notice informs us of ReviveBio's view that this use of autoclaved *P. goldsteinii* "RV-01" is GRAS through scientific procedures.

In an email dated December 11, 2025, we communicated with you as a ReviveBio's representative regarding additional information needed to support a GRAS conclusion. We noted that there is no history of long-term safe consumption of *P. goldsteinii* in food. We acknowledged that ReviveBio has a toxicological study that reports a lack of toxicity for this substance; however, other preclinical animal studies suggest that *P. goldsteinii* has potential therapeutic applications (see references). These studies raise safety questions about the uncharacterized physiological activities of the substance. The questions concern the potential for metabolic regulation, immunomodulatory effects, regulation of inflammation, and gut microbiome alterations. We noted that ingredients added to food must be safe for long-term consumption by the general population, including sensitive subpopulations.

We have ceased our evaluation of the notice at your request on behalf of ReviveBio. We remind ReviveBio of a manufacturer's responsibility to ensure the safety and regulatory status of the substance that it markets for use in food or that it uses in food. We also remind ReviveBio that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the

criteria for GRAS is available in our regulations (21 CFR part 170).

Finally, we remind ReviveBio of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which ReviveBio agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001277 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2026.01.22 10:28:20 -05'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program

References:

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